

Notice of Allowability

Application No.

10/523,208

Examiner

Jason M. Nolan, Ph.D.

Applicant(s)

MEHTA ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/01/2007.
2. ☒ The allowed claim(s) is/are 1-4, 6 and 8-10 (now 1-8).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>PTOL-413B</u> . |

DETAILED ACTION

Claims 1-4, 6 & 8-10 are pending in the instant application, of which **Claims 1, 2, 4, 6 & 8** are currently amended. **Claims 5 & 7** are cancelled.

Response to Amendment

Applicant's amendments, see Amendment – After Non-Final Rejection, filed 03/01/2007, with respect to **Claims 1, 2, 4, 6 & 8** have been fully considered and are entered. The 112-enablement rejection of the Non-Final Rejection, 12/21/2006, has been withdrawn.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with George Heibel on April 18, 2007.

The application has been amended as follows:

1. In **Claim 4**, after "...urinary incontinence, lower urinary tract symptoms (LUTS)," and before "or gastro intestinal hyperkinesis" delete "bronchial asthma, chronic obstructive pulmonary disorders (COPD), pulmonary fibrosis, irritable bowel syndrome, obesity, diabetes" and insert - - chronic obstructive pulmonary disorders (COPD), irritable bowel syndrome - -.

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2. In **Claim 6**, after "...urinary incontinence, lower urinary tract symptoms (LUTS)," and before "gastro intestinal hyperkinesis" delete "bronchial asthma, chronic obstructive pulmonary disorders (COPD), pulmonary fibrosis, irritable bowel syndrome, obesity, diabetes and" and insert - - chronic obstructive pulmonary disorders (COPD), irritable bowel syndrome or - -.

Statement of Reasons for Allowance

The present invention pertains to the compounds of Formula I, methods of making such compounds, and methods of using these compounds (or compositions) for the treatment of urinary incontinence, lower urinary tract symptoms (LUTS), chronic obstructive pulmonary disorders (COPD), irritable bowel syndrome or gastrointestinal hyperkinesis. The compounds according to Formula I are free of the prior art; nothing known in the art anticipates or renders the compounds of the instant application obvious. Besides the work of the inventors, no prior art has been shown to contain a compound comprising the bicyclic nitrogen heterocyclic core and a substituted alkyl chain on the nitrogen atom as shown in Formula I.

The compounds of Formula I are muscarinic receptor antagonists (see specification, pp. 24-27 for biological assays: *in vitro* and *in vivo* model studies therein). The use of muscarinic receptor antagonists for the treatment of respiratory, urinary, and gastrointestinal diseases has been well studied in the art. The publication by Eglen *et al.* (*Current Opinion in Chemical Biology* **1999**, 3, 426-432; **IDS**) discusses the therapeutic potential for muscarinic receptor antagonists in the treatment of respiratory and gastrointestinal diseases. Another publication by Birdsall *et al.* (*Trends in*

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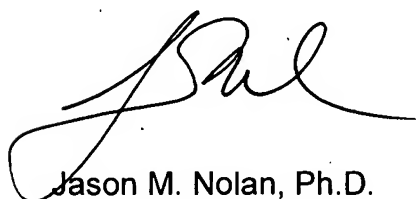
Pharmacological Sciences **2001**, 22(5), 215-219; **IDS**) discusses treatments for respiratory and gastrointestinal diseases. Further, muscarinic receptor antagonists have been well studied for the treatment of urinary diseases and are currently marketed for the treatment of lower urinary tract symptoms, (see Chapple, C.R. *Urology*, **2000**, 55, 33-46; **IDS**).

One skilled in the art would be enabled to make and use the compounds taught herein for the purpose of treating the cancers listed above using the teachings of the specification in conjunction with the teachings in the prior art.

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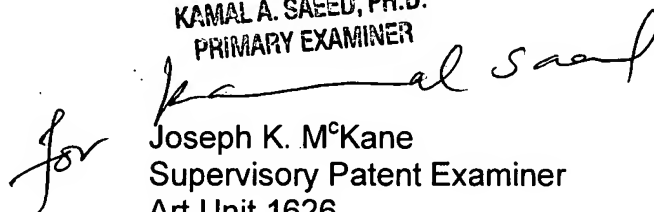
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



for

Joseph K. M^cKane
Supervisory Patent Examiner
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Date: April 18, 2007